

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):



- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support (SIRA)

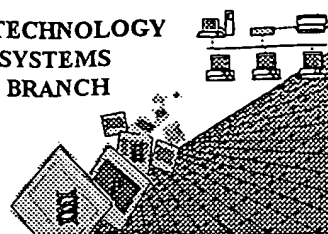
Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

1645

BIOTECHNOLOGY
SYSTEMS
BRANCH



RAW SEQUENCE LISTING
ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/612,925B
Source: 1600
Date Processed by STIC: 7/24/2002

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TECH CENTER 1600/2900

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OCT 21 2002

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THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: patin21help@uspto.gov or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: patin3help@uspto.gov or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE **CHECKER**
VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND
TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebs/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Hand Carry directly to:
U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7th Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202
Or
U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202

Revised 01/29/2002

Raw Sequence Listing Error Summary

ERROR DETECTED

SUGGESTED CORRECTION

SERIAL NUMBER: 09/612925B

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics
 Wrapped Aminos The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
- 2 Invalid Line Length The rules require that a line not exceed 72 characters in length. This includes white spaces.
- 3 Misaligned Amino
 Numbering The numbering under each 5th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
- 4 Non-ASCII The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
- 5 Variable Length Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
- 6 PatentIn 2.0
 "bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) . Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
- 7 Skipped Sequences
 (OLD RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence:
 (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
 (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading)
 (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown)
 This sequence is intentionally skipped

 Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
- 8 Skipped Sequences
 (NEW RULES) Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence.
 <210> sequence id number
 <400> sequence id number
 000
- 9 Use of n's or Xaa's
 (NEW RULES) Use of n's and/or Xaa's have been detected in the Sequence Listing.
 Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present.
 In <220> to <223> section, please explain location of n or Xaa; and which residue n or Xaa represents.
- 10 Invalid <213>
 Response Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
- 11 Use of <220> Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses.
 Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section.
 (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
- 12 PatentIn 2.0
 "bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
- 13 Misuse of n n can only be used to represent a single nucleotide in a nucleic acid sequence. N is not used to represent any value not specifically a nucleotide.



1645

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/612,925B

DATE: 07/24/2002
TIME: 14:24:11

Input Set : A:\sequence listing.txt
Output Set: N:\CRF3\07242002\I612925B.raw

P.4

Does Not Comply
Corrected Diskette Needed

3 <110> APPLICANT: Cano, Carlos Antonio Durante
4 Nieto, Enrique Gerardo Guillen
5 Acosta, Anabel Alvarez
6 Munoz, Luis Emilio Carpio
7 Vazquez, Diogenes Quintana
8 Rodriguez, Carmen Elena Gomez Rodriguez
9 Rodriguez, Recardo de la Caridad Siva
10 Galvez, Consuelo Nazabal
11 Angulo, Maria de Jesus Leal
12 Dunn, Alejandro Miguel Martin
14 <120> TITLE OF INVENTION: System for the Expression of Heterologous Antigens as Fusion Proteins
16 <130> FILE REFERENCE: LEXSA P-13DIV2
18 <140> CURRENT APPLICATION NUMBER: 09/612,925B
19 <141> CURRENT FILING DATE: 2000-07-10
21 <150> PRIOR APPLICATION NUMBER: 08/930,917
22 <151> PRIOR FILING DATE: 1997-09-16
24 <150> PRIOR APPLICATION NUMBER: CU97/00001
25 <151> PRIOR FILING DATE: 1997-01-17
27 <160> NUMBER OF SEQ ID NOS: 21
29 <170> SOFTWARE: PatentIn version 3.1
31 <210> SEQ ID NO: 1
32 <211> LENGTH: 47
33 <212> TYPE: PRT
34 <213> ORGANISM: Neisseria meningitidis
36 <400> SEQUENCE: 1
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39 1 5 10 15
42 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
43 20 25 30
46 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Glu Thr Asp
47 35 40 45
50 <210> SEQ ID NO: 2
51 <211> LENGTH: 18
52 <212> TYPE: PRT
53 <213> ORGANISM: Neisseria meningitidis
55 <400> SEQUENCE: 2
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58 1 5 10 15
61 Ala Gly
65 <210> SEQ ID NO: 3
66 <211> LENGTH: 18
67 <212> TYPE: PRT
68 <213> ORGANISM: Neisseria meningitidis

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TECH CENTER 1600/2900

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/612,925B

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73 1 5 10 15
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83 <213> ORGANISM: Neisseria meningitidis
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88 1 5 10 15
91 Ala Ala Gly Gly Ala Thr Cys Cys Gly Ala
92 20 25
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96 <211> LENGTH: 146
97 <212> TYPE: PRT
98 <213> ORGANISM: Neisseria meningitidis
100 <400> SEQUENCE: 5
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103 1 5 10 15
106 Ala Gly Ala Ala Thr Gly Gly Cys Thr Thr Thr Ala Gly Thr Thr Gly
107 20 25 30
110 Ala Ala Thr Thr Gly Ala Ala Ala Gly Thr Gly Cys Cys Cys Gly Ala
111 35 40 45
114 Cys Ala Thr Thr Gly Gly Cys Gly Gly Ala Cys Ala Cys Gly Ala Ala
115 50 55 60
118 Ala Ala Thr Gly Thr Ala Gly Ala Thr Ala Thr Ala Thr Cys Gly
119 65 70 75 80
122 Cys Gly Gly Thr Thr Gly Ala Ala Gly Thr Ala Ala Ala Cys Gly Thr
123 85 90 95
126 Gly Gly Gly Cys Gly Ala Cys Ala Cys Thr Ala Thr Thr Gly Cys Thr
127 100 105 110
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135 130 135 140
138 Ala Ala
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145 <213> ORGANISM: Neisseria meningitidis
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153 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
154 20 25 30
157 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Glu
158 35 40 45

RAW SEQUENCE LISTING
PATENT APPLICATION: US/09/612,925B

DATE: 07/24/2002
TIME: 14:24:11

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163 <212> TYPE: PRT
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173 <211> LENGTH: 16
174 <212> TYPE: PRT
175 <213> ORGANISM: Neisseria meningitidis
177 <400> SEQUENCE: 8
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185 <212> TYPE: PRT
186 <213> ORGANISM: Human immunodeficiency virus type 1
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196 <212> TYPE: PRT
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205 <210> SEQ ID NO: 11
206 <211> LENGTH: 15
207 <212> TYPE: PRT
208 <213> ORGANISM: Human immunodeficiency virus type 1
210 <400> SEQUENCE: 11
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216 <210> SEQ ID NO: 12
217 <211> LENGTH: 15
218 <212> TYPE: PRT
219 <213> ORGANISM: Human immunodeficiency virus type 1
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228 <211> LENGTH: 15
229 <212> TYPE: PRT
230 <213> ORGANISM: Human immunodeficiency virus type 1
232 <400> SEQUENCE: 13
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235 1 5 10 15
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RAW SEQUENCE LISTING

DATE: 07/24/2002

PATENT APPLICATION: US/09/612,925B

TIME: 14:24:11

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Output Set: N:\CRF3\07242002\I612925B.raw

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 250 <211> LENGTH: 15
 251 <212> TYPE: PRT
 252 <213> ORGANISM: Human immunodeficiency virus type 1
 254 <400> SEQUENCE: 15
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 257 1 5 10 15
 260 <210> SEQ ID NO: 16
 261 <211> LENGTH: 15
 262 <212> TYPE: PRT
 263 <213> ORGANISM: Human immunodeficiency virus type 1
 265 <400> SEQUENCE: 16
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 272 <211> LENGTH: 5
 273 <212> TYPE: PRT
 274 <213> ORGANISM: unidentified
 276 <400> SEQUENCE: 17
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 279 1 5
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 283 <211> LENGTH: 141
 284 <212> TYPE: PRT
 285 <213> ORGANISM: Human immunodeficiency virus type 1
 287 <400> SEQUENCE: 18
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 290 1 5 10 15
 293 His Leu Leu Leu Asp Leu Gln Ile Phe Leu Ser Arg Gly Ile Arg Ile
 294 20 25 30
 297 Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly Gly Gly Ala Arg Gln
 298 35 40 45
 301 Ser Thr Pro Ile Gly Leu Gly Gly Ala Leu Tyr Thr Thr Ala Gly Gly
 302 50 55 60
 305 Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly Arg Val Ile Tyr Ala
 306 65 70 75 80
 309 Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His Ile Gly Pro Gly Arg
 310 85 90 95
 313 Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile Thr Met
 314 100 105 110
 317 Gly Pro Gly Arg Val Tyr Tyr Thr Thr Ala Gly Gly Gly Ala Ser Ile
 318 115 120 125

inhib response - see item 10 on Eval

Summary

Sheet

RAW SEQUENCE LISTING

DATE: 07/24/2002

PATENT APPLICATION: US/09/612,925B

TIME: 14:24:11

Input Set : A:\sequence listing.txt

Output Set: N:\CRF3\07242002\I612925B.raw

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327 <212> TYPE: PRT
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336 Gly Gly His Glu Asn Val Asp Ile Ile Ala Val Glu Val Asn Val Gly
337           20           25           30
340 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Asp Ser
341           35           40           45
344 Arg Gly Ile Arg Ile Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly
345           50           55           60
348 Gly Gly Ala Arg Gln Ser Thr Pro Ile Gly Leu Gly Gly Ala Leu Tyr
349 65           70           75           80
352 Thr Thr Ala Gly Gly Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly
353           85           90           95
356 Arg Val Ile Tyr Ala Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His
357           100          105          110
360 Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg
361           115          120          125
364 Lys Arg Ile Thr Met Gly Pro Gly Arg Val Tyr Tyr Thr Thr Ala Gly
365           130          135          140
368 Gly Gly Ala Ser Ile Arg Ile Gln Arg Gly Pro Gly Arg Ala Phe Val
369 145          150          155          160
372 Thr Ile
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378 <212> TYPE: PRT
379 <213> ORGANISM: Human immunodeficiency virus type 1
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388           20           25           30
391 Asp Thr Ile Ala Val Asp Asp Thr Leu Ile Thr Leu Asp Leu Asp Ser
392           35           40           45
395 Arg Gly Ile Arg Ile Gly Pro Gly Arg Ala Ile Leu Ala Thr Ala Gly
396           50           55           60
399 Gly Gly Ala Arg Gln Ser Thr Pro Ile Gly Leu Gly Gln Ala Leu Tyr
400 65           70           75           80
403 Thr Thr Ala Gly Gly Gly Ala Arg Lys Ser Ile Thr Lys Gly Pro Gly
404           85           90           95
407 Arg Val Ile Tyr Ala Thr Ala Gly Gly Gly Ala Arg Lys Arg Ile His
408           100          105          110
411 Ile Gly Pro Gly Arg Ala Phe Tyr Thr Thr Ala Gly Gly Gly Ala Arg
412           115          120          125

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VERIFICATION SUMMARY

PATENT APPLICATION: US/09/612,925B

DATE: 07/24/2002

TIME: 14:24:12

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